CENEBA
BIOPROCESS

LIFE SCIENCES**BIOANALYTICAL SERVICES**

CENEBA BIOPROCESS, a Mexican laboratory, has vast experience in analytical and bioanalytical method development and validation for a variety of platforms including HPLC, LC/MS/MS, GC/MS, GC/FID, UPLC, and ligand binding assays (MSD, ELISA or other cell-based assays).

As both an in vivo, analytical chemistry and bioanalytical CRO, we support product development of a variety of pharmaceuticals, biologics and medical devices at all stages of the product life cycle.

Method development and validation is an important first step to determine that analytes of interest can be reliably detected and quantified for routine sample analysis. Our team includes three lead scientists that each have over 10 years experience in method development and validation.

They will work with you to understand your needs and develop a plan for your product's analytical development. Based on our extensive experience with similar products and by drawing upon published literature resources, CENEBA BIOPROCESS can swiftly develop the most appropriate method for your product.

Email: contacto@ceneba.com
Phone: +52-33-23-16-42-80
Jalisco, México CP 45640

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LIFE SCIENCES**METHOD DEVELOPMENT AND VALIDATION SERVICES**

To help you with pharmaceutical method development and validation processes, we offer development and documentation of analytical protocols and reports for proprietary and non-proprietary test methods and manufacturing processes. This is conducted in compliance with the Notes for Guidance Validation of Analytical Procedures, Definitions and Terminology and Validation of Analytical Procedures Methodology by the ICH (Q2A, Q2B) and FDA and COFEPRIS guidelines.

Once a method is validated, it may require transfer. Method transfer may involve comparative testing, co-validation between two sites (lab-to-lab), complete or partial revalidation and comprehensive documentation (transfer plan, protocol and report).

WHY CHOOSE METHOD DEVELOPMENT OPTIMIZATION AND VALIDATION FROM CENEBA BIOPROCESS?

Whether we are the developing or the receiving laboratory, we can assist you with your method transfer requirements.

Our method development and validation services include:
•Bioanalytical assays, Identification, Assay testing, Testing for impurities, Stability indicating methods, Moisture content, pH values, Light stressing, Microbial testing, Particle size analysis.

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LIFE SCIENCES**METHOD DEVELOPMENT AND VALIDATION SERVICES**

TRUSTED METHOD DEVELOPMENT OPTIMIZATION AND VALIDATION FROM A MEXICAN-LEADING PROVIDER

As world leader in testing, inspection, verification and certification, we offer you extensive experience in pharmaceutical method development and validation.

Typical method validation will include the following tests:

•System suitability test
•Accuracy
•Precision
•Precision
•Specificity (including forced degradation where applicable)
•Detection limit
•Quantitation limit
•Linearity
•Range
•Robustness (including stability)

To discuss your method development optimization and validation requirements, call us today.

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